

REMARKS

I. STATUS OF THE CLAIMS

Claims 1, 4, 5 and 7-21 are pending in the Application. Applicant respectfully notes that the previous rejections under 35 U.S.C. §112 and under 35 U.S.C. §102 over Stillman have been withdrawn. All pending claims stand rejected. All claims have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. All claims have been rejected under 35 U.S.C. § 112, second paragraph, as failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. All claims have been rejected under 35 U.S.C. §103(a) as obvious.

II. AMENDMENTS TO THE CLAIMS

Claims 1 and 21 are herein amended. Applicant is not conceding in this Application that the amended claims are not patentable, as the present claim amendments are only for facilitating expeditious prosecution of the allowable subject matter noted by the Examiner. Applicant respectfully reserves the right to pursue these and other claims in one or more continuation or divisional patent applications.

Claim 1 step (a) and Claim 21 step (a) have been amended to the following form:

contacting a C₅ to C₇ polyol with a protein contained in a spotting solution or being present on an array, wherein said polyol is between 0.5 and 10% of the spotting solution, and wherein the polyol is a linear molecule that is ~~linked to other molecules~~ and is [[a]]mannitol, maltitol, or sorbitol.

The deletions add no new matter, and are made in compliance with the Examiner's rejections under 35 U.S.C. § 112, discussed below. Applicant respectfully requests the Examiner enter the amendment.

Claim 1 step (b) and Claim 21 step (b) have been amended to the following form:

depositing the spotting solution on one of the discrete analyte-specific regions of the surface of a nonporous solid support resulting in covalent binding of the capture proteins to the support, wherein the surface of the nonporous solid support comprises a reactive group capable of reacting with an amino group in the capture protein, and wherein the covalent binding occurs between an amino group in the protein and the reactive group.

The added text is supported by paragraph [0044] of the published Application. The addition adds no new matter. Applicant respectfully requests the Examiner enter the amendment.

III. PETITION UNDER 37 C.F.R. § 1.181, REQUEST FOR RECONSIDERATION

In Applicant's Remarks filed May 21, 2007, Applicant respectfully requested the Office provide an English translation of the non-English reference of Guo. The Examiner has declined to grant the request. Office Action, pages 10-11. The Board of Patent Appeals and Interferences held in *Ex parte Jones*, 62 U.S.P.Q.2d 1206, 1208 (TTAB 2001) that "If a translation is not supplied by the examiner, the applicant may wish to consider seeking supervisory relief by way of a petition (37 CFR § 1.181) to have the examiner directed to obtain and supply a translation."

Among the requirements of 37 CFR § 1.181 is the following:

(c) When a petition is taken from an action or requirement of an examiner in the ex parte prosecution of an application, or in the ex parte or inter partes prosecution of a reexamination proceeding, it may be required that there have been a proper request for reconsideration (§ 1.111) and a repeated action by the examiner. The examiner may be directed by the Director to furnish a written statement, within a specified time, setting forth the reasons for his or her decision upon the matters averred in the petition, supplying a copy to the petitioner.

In compliance with the requirements of 37 CFR § 1.181, Applicant hereby requests reconsideration of the Examiner's refusal to provide an English translation of Guo as required under MPEP 706.02 part II and *Ex parte Jones*, 62 USPQ2d 1206 (BPAI 2001).

As set forth in Applicant's Remarks filed May 21, 2007, the requirement that the Examiner provide an English translation when an abstract of a foreign-language document has been relied upon in a rejection has been incorporated in the MPEP at section 706.02 Part II:

When an abstract is used to support a rejection, the evidence relied upon is the facts contained in the abstract, not additional facts that may be contained in the underlying full text document. Citation of and reliance upon an abstract without citation of and reliance upon the underlying scientific document is generally inappropriate where both the abstract and the underlying document are prior art. See *Ex parte Jones*, 62 USPQ2d 1206, 1208 (Bd. Pat. App. & Inter. 2001) (unpublished). To determine whether both the abstract and the underlying document are prior art, a copy of the underlying document must be obtained and analyzed. If the document is in a language other than English and the examiner seeks to rely on that document, a translation must be obtained so that the record is clear as to the precise facts the examiner is relying upon in support of the rejection. [Emphasis added]

Applicant respectfully requests the Examiner provide an English translation of the alleged prior art reference. Applicant's ability to respond to the Office Action is hindered, because references have been made to the abstract of a foreign-language patent. The Applicant makes no admission that the cited foreign language document constitutes prior art. If the Examiner does not provide English translations as required by *Ex parte Jones*, then the Applicant respectfully requests the Examiner withdraw the rejections of the claims over Guo.

IV. REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claims 1, 4-5 and 7-21 have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Office Action indicates that the claimed subject matter was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. According to the Office Action, the claimed "other

molecules" is not supported in the application as filed. In response, Applicant has deleted the words "linked to other molecules" from claims 1 and 21.

Applicant respectfully requests the Examiner reconsider the rejection. As Applicant has deleted the rejected language, Applicant submits the rejection is now moot. Accordingly, Applicant respectfully requests the Examiner withdraw the rejection and allow the claims.

V. REJECTIONS UNDER 35 U.S.C. §112, SECOND PARAGRAPH

Claims 1, 4-5 and 7-21 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

According to the Office Action,

1. Claim 1, step a) is not clear whether mannitol, maltitol or sorbitol is the linked polyol or unlinked polyol that is being linked to other molecules to produce mannitol, maltitol or sorbitol.
2. Claim 1 is indefinite as to the metes and bounds of the claimed "other molecules." The specification does not define what is included or precluded by said other molecules, absent distinguishing or characterizing features of said "other molecules."

In response, Applicant has deleted the words "linked to other molecules" from claims 1 and 21. Applicant respectfully requests the Examiner reconsider the rejection. As Applicant has deleted to rejected language, Applicant submits the rejection is now moot. Accordingly, Applicant respectfully requests the Examiner withdraw the rejection and allow the claims.

VI. REJECTIONS UNDER 35 U.S.C. § 103

Claims 1, 4-5 and 7-21 have been rejected under 35 U.S.C. §103(a) as being unpatentable over any one of Great Britain Publication No. 2,016,687A to Decker ("Decker") or International Publication No. WO 93/07466 to Devereaux ("Devereaux") or U.S. Publication No. 2003/0175827 to Stillman et al. ("Stillman") in view of either Guo (Faming Zhuanli Shenqing Gongkai) ("Guo") or U.S. Publication No. 2003/0134294 to Sandford et al. ("Sandford") and U.S. Publication No. 2004/0198637 to Schultz et al. ("Schultz").

Applicant respectfully traverses the rejection.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). MPEP 2142.

The current amendments to Claims 1 and 21 introduce a claim limitation that is not taught or suggested by the cited references in combination. Furthermore, Applicant submits there was no motivation to combine the cited references.

A. The Cited References Do Not Teach Every Element of the Claims

As stated above, a rejection under 35 U.S.C. §103 requires the prior art reference (or references when combined) must teach or suggest all the claim limitations.

As stated in Section II above, Claims 1 and 21 now include the following limitation:

...wherein the surface of the nonporous solid support comprises a reactive group capable of reacting with an amino group in the capture protein, and wherein the covalent binding occurs between an amino group in the protein and the reactive group.

This element is not found in the references cited by the Examiner. The Office Action relies on Schultz to teach covalent bonding between a capture protein and a solid support surface. Office Action, pages 7-8. However, Schultz teaches the formation of a covalent bond between a component of the solid support and a side group of an "unnatural" amino acid, the side group being a nucleophilic moiety. See paragraphs [0009] and [0017] of Schultz for a list of suitable nucleophilic moieties.

Schultz's invention allows a side group of a specific unnatural amino acid to bind to a solid support:

The invention provides protein arrays where a polypeptide is attached to a solid support, and where the polypeptide incorporates at least one unnatural amino acid and the polypeptide is attached to the solid support by a chemical linkage that is formed from the reaction product between a first reactive group that is on the side chain of the unnatural amino acid and a second reactive group that is attached to a solid support.

Schultz, paragraph [0008]. The purpose of Schultz's invention is to provide specific covalent bonding between only the unnatural amino acid and a reactive group on the solid surface. One skilled in the art would understand that Schultz does not teach employment of a reactive group on the solid surface that will form a covalent bond with a natural amino acid; this would sacrifice the specificity that is the goal of Schultz.

In the claimed embodiment, the unmodified amino terminal end of a protein or an amino group in the side chain of a natural amino acid will bind to an active group on the solid surface. Thus the claimed mechanism of covalent binding is distinct from that of Schultz. The claimed embodiment has the advantage of not requiring any modification of the capture protein prior to

covalent bonding of the capture protein to the solid surface. This reduces the time and labor required by the method.

Applicant recognizes that Sandford teaches covalent binding between proteins and active groups in a hydrogel matrix. However, Applicant claims binding between an amino group and a solid surface, not a gel matrix.

Applicant respectfully requests the Examiner reconsider the rejection. As stated above, the references in combination do not teach every element of Claims 1 and 21. Claims 4, 5, and 7-20 depend on Claim 1. As Claim 1 is not obvious in light of the cited references, Claims 4, 5, and 7-20 are not obvious in light of the cited references. Accordingly, Applicant respectfully requests the Examiner withdraw the rejection and allow the claims.

B. There was No Motivation to Combine the References

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so. *In re Kahn*, 441 F.3d 977, 986, 78 USPQ2d 1329, 1335 (Fed. Cir. 2006) (discussing rationale underlying the motivation-suggestion-teaching requirement as a guard against using hindsight in an obviousness analysis). The teaching, suggestion, or motivation must be found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. "The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art." *In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000). *See also In re Lee*, 277 F.3d 1338, 1342-44, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002) (discussing the importance of relying on objective evidence and making specific factual findings with respect to the motivation

to combine references); *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

Applicant submits there was no motivation to combine the cited references, for the reasons described for each reference below.

1. Rejection as it Relates to Devereaux

If a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). MPEP 2143.01.

The purpose of Devereaux is to provide a stable dried form of capture protein that may be rehydrated and released into solution. Devereaux teaches the immobilization of the capture protein within a gelatin matrix, and teaches that the capture protein will then be released into solution at the time of the assay.

The claimed invention is intended to maintain the capture protein on the solid support during the assay, so as prevent the protein from being released into solution. Modifying Devereaux as the Examiner suggests to create the Applicant's invention would render Devereaux useless for its intended purpose: the release of protein probes into solution after extended storage. As the proposed modification of Devereaux would render Devereaux unsatisfactory for its intended purpose, Applicant submits there was no suggestion or motivation to make the proposed modification.

2. Rejection as it Relates to Stillman

Stillman teaches away from the claimed embodiments. Stillman teaches the use of denaturing surfaces, which are likely to diminish the capture protein's activity. It would not be

obvious to modify the invention of Stillman to create the Applicant's invention, because Stillman's method involves denaturing the protein, and the goal of the Applicant's invention is to preserve the protein in its native conformation. Because Stillman's use of denaturing surfaces will denature the proteins' native conformation, Stillman teaches away from the Applicant's invention.

3. Rejection as it Relates to Guo

As discussed above in Section III, the reliance on the English abstract of an un-translated non-English reference, such as Guo, is improper under U.S. Patent and Trademark Office procedure. Applicant respectfully requests the Examiner reconsider his declination to provide an English translation of Guo. In the absence of a translation, Applicant respectfully requests the rejection in view of Guo be withdrawn.

4. Rejection as it Relates to Sandford

If a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). MPEP 2143.01.

The purpose of Sandford is to provide a stable hydrogel matrix to which biological materials are immobilized (covalently bound) in a hydrated three-dimensional hydrogel matrix. Sandford assures the preserved activity of the biological material by immobilizing the biological material in the semi-aqueous medium of the hydrogel.

The claimed embodiments are directed to proteins linked to a support system for the particular purpose of drying the proteins. Sandford's invention is directed to keeping proteins in an aqueous environment, and points out the need to prevent drying (see particularly paragraph

[0274] of Sandford, in which a step is taken to prevent drying). The structure of a hydrogel matrix is destroyed upon drying. The claimed embodiments teach a method of preserving activity upon drying, whereas Sandord teaches a method of preventing drying in the first place. If Sandford were modified as the Examiner suggests, then the invention of Sandford would be useless for its intended purpose. Applicant therefore submits there is no suggestion or motivation to make the proposed modification.

In view of the foregoing remarks, Applicant respectfully requests that the rejections under 35 U.S.C §103 be withdrawn.

VII. CONCLUSION

Applicant submits that all claims are patentably distinguishable over the prior art for the reasons explained above. As such, Applicant respectfully requests the Examiner reconsider and withdraw all rejections, and allow all claims.

The Commissioner for Patents is hereby authorized to charge the amount due for the Request for Continued Examination, the amount for any deficiency in any fees due with the filing of this paper, and credit any overpayment in any fees paid on the filing or during prosecution of this application to Deposit Account No. 50-0951.

Applicant is grateful for the Examiner's consideration of this matter. In light of the remarks above, Applicant respectfully requests the Amendments be entered, all rejections be withdrawn, and all claims be allowed. If the Examiner still has concerns as to the allowability of any claims, the Examiner is urged to telephonically contact the undersigned at the number below.

Respectfully submitted,

Date: Jan. 8, 2008

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